K012904

SEP 21 2001

510(k) Summary of Safety and Effectiveness

The following information provides data supporting a substantially equivalent determination between the ADVIA 120 Cn-free Hgb Method and the ADVIA 120 cyanide containing Hgb predicate method (K971998).

Intended Use

The ADVIA 120 Cn-free Hgb Method is intended to provide an *in vitro* diagnostic, quantitative measurement of hemoglobin concentration in a sample of whole blood.

Device Description

The ADVIA 120 Cn-free Hgb Method consists of the following optional changes to the ADVIA 120 Hematology System:

1. A reformulated reagent used to measure hemoglobin without the use of potassium cyanide.
2. A special cap and straw for the reagent bottle that restricts air exchange with the reagent.
3. A modified colorimeter that measures the hemoglobin reaction at 565 nm.
4. Modified software to implement the algorithms necessary to calculate hemoglobin concentration when using the optional reagent and hardware for the method.

Principles of Operation

When using the ADVIA 120 Cn-free Hgb Method, the blood sample is diluted 1:250 with diluent. The diluent contains an ionic surfactant which is dissolved in NaOH. The surfactant causes hemolysis of red cells, plus emulsification of cellular debris and plasma lipids. Following the release of hemoglobin by hemolysis, the combined action of alkaline pH and surfactant results in rapid denaturation of the protein with release of the hemes. The hemes then undergo air oxidation of heme iron to the iron III state and coordinate one hydroxide ion and one water molecule as axial ligands to form monoaquomonohydroxyiron III-porphyrin. The diaxial-coordinated hemes are then incorporated into surfactant micelles to yield the reaction product. Absorbance is measured at approximately 565 nm in a colorimeter flow cuvette, with an 8-mm light path.

Similarities and Differences between the ADVIA 120 Cn-free Hgb Method and the ADVIA 120 Cyanide Containing Hgb Predicate Method (K971998)

The following table provides similarities and differences between the ADVIA 120 Cn-free Hgb Method and the ADVIA 120 cyanide containing predicate method.

Similarities/Differences	Characteristic	ADVIA 120 Cyanide Containing Method	ADVIA 120 Cn-free Method
Similarities	Intended Use	To provide a quantitative measurement of hemoglobin concentration in whole blood.	Same as predicate method.
	Calibrator Material	ADVIA SETpoint Calibrator	Same as predicate method.
	Quality Control Materials	ADVIA TESTpoint Hematology Controls	Same as predicate method.
	Accuracy	As specified in product labeling.	Equivalent to predicate method.
	Precision	As specified in product labeling.	Equivalent to predicate method.
	Linearity	As specified in product labeling.	Equivalent to predicate method.
	Carryover	As specified in product labeling.	Equivalent to predicate method.
Differences	Reagent and System Effluent	Hgb reagent and system effluent contain cyanide.	Hgb and system effluent do not contain cyanide.
	Absorbance Measurement	Measured at 546 nm.	Measured at 565 nm.
	Air Exchange with Reagent	No precaution taken.	Restricted air exchange using specially designed cap and straw for reagent bottle.

Conclusion

The test results included in this submission demonstrate that the ADVIA 120 Cn-free Hgb Method has equivalent accuracy, precision, linearity, and carryover similar to the ADVIA 120 predicate method.

Date 8/20/01

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 2 1 2001

Kenneth T. Edds, Ph.D.
Manager, Regulatory Affairs
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Re: K012904
Trade/Device Name: Cyanide-Free Hemoglobin Determination Option for the Advia 120 Hematology Analyzer
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: II
Product Code: GKZ
Dated: August 29, 2001
Received: August 29, 2001

Dear Dr. Edds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K012904

Device Name: Cyanide-free Hemoglobin Determination Option for the Advia 120 Hematology Analyzer

Indications for Use: The Advia 120 Cn-free Hgb method is intended to quantitatively measure hemoglobin concentration in a sample of whole blood.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012904

Prescription Use ✓ OR Over-The-CounterUse _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)